Amendments to the Drawings:

The attached four sheets of drawings, depicting Figs. 1-5, replace the original sheets for Figs. 1-5. For all four drawing sheets, the caption has been replaced, and in Figures 1, 2 and 5, the sequence identifiers for each of the amino acid sequences presented therein has been included. These changes are supported by the specification and sequence listing and do not constitute new matter.

Attachment: Replacement Formal Drawings

REMARKS

Applicants have submitted a Substitute Sequence Listing and replacement Figures, and Applicants have submitted amendments to the specification primarily to ensure the incorporation of appropriate sequence identifiers for the amino acid sequences listed in the specification, drawings and claims, pursuant to 37 C.F.R. § 1.821(d). Applicants assert that the changes in the Substitute Sequence Listing, figures and specification do not constitute new matter.

Claims 1-8 and 17-24 were pending for this application. Applicants have herewith amended claims 1, 3-6, 17 and 19-24. The amended claims are fully supported by the original application as filed and do not constitute new matter.

1. The Rejection Under 35 U.S.C. §112, Second Paragraph ("Definiteness"), Should Be Withdrawn

The Examiner has rejected claims 1-8 and 17-24 for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention, under 35 U.S.C. § 112, second paragraph.

First, the Examiner believes that the reference in pending claims 1, 7, 23 and 24 to "native" amino acid sequence is potentially confusing and the Examiner offers suggestions as to how that the applicable claims might be amended to render the scope clearly. Applicants appreciate the Examiner's suggestions and note that the language of the applicable claims has been presently amended such that the term "native" is no longer recited in the claims as such and that the sequences of the claims are more particularly identified.

Second, the Examiner believes that claims 4 and 20 are confusing in the use of the term "C-terminal" with reference to the heptad repeat positions of the claims. Applicants respect the Examiner's views and note that these claims have been amended in an effort to promote the clarity of the claims. Applicants observe that the "C-terminal" term refers to the latter position (toward the "C" terminus of a sequence) in the hydrophobic domain of the HR1 region, i.e., the second such "e" or "f" in the pattern of "efgabcdef" (e.g., wherein the underlined e and f are in amino acid residue positions 35 and 36 of an HR1 hydrophobic domain spanning positions 28 to 36), or, as the "pattern" may be alternatively stated: "e_8" and "f_9" from "$e_1f_2g_3a_4b_5c_6d_7e_8f_9$". Applicants have amended the applicable claims such that the term "C-terminal" is no longer recited as before. Applicants trust that the claim amendments more clearly render the appropriate residue substitutions referenced by the claims so as to alleviate the Examiner's concerns about clarity of these claims.

Third, the Examiner believes that the use of the claim terms "one or more reactive functionalities" and "amino acid substitution comprising an addition" render claims 6 and 22 vague and indefinite. The Examiner observes, in particular, that while the term "reactive functionalities" is defined in the specification, limitations from the specification are not read into the claims. In response, Applicants note that the claim term "reactive functionalities" has been replaced in these claims with language that more precisely describes what groups may constitute "reactive functionalities." Applicants further note that the applicable claims have been amended so as to help distinguish "addition[s]" as being modifications (rather than "substitutions") and, likewise, to distinguish an initial substitution made within a sequence region from a further "additional" substitution. Applicants hope that the present amendments have addressed the Examiner's concerns and serve to obviate the present rejection under 35 U.S.C. § 112, second paragraph. Applicants thus ask that the Examiner reconsider and withdraw this rejection.

2. The Rejection Under 35 U.S.C. § 103(a) Based On Bewley et al. (2002) in View of Ferrer et al. (1999) Should Be Withdrawn

The Examiner rejects claims 1, 4, 7, 8, 17, 20, 23 and 24 as allegedly rendered obvious by Bewley et al. (2002) in view of Ferrer et al. (1999). Bewley purportedly discloses a synthetic peptide from the HR1 region of HIV-1 gp41 with potent antiviral activity and featuring substitutions at designated ("e" and "f") heptadic positions, while Ferrer purportedly discloses a screening method to help identify small molecule inhibitors of HIV-1 using an HR1/HR2 binding assay.

In response, Applicants note that the applicable claims have been amended to more clearly delineate that which Applicants consider to be the subject matter of the present invention, including articulating particular sequences and particular polymorphisms thereof, and substitutions thereto, that constitute the initial materials (i.e., peptides useful for the assay) for use in the invention. Applicants have also addressed the length of subject peptides of the present claims such that the peptides of the invention are clearly different and longer than the two 36-mer peptides with narrowly limited and particular substitutions disclosed in Bewley, and have identified the particular heptad repeat amino acid domain or "cluster" within the HR1 sequence wherein substitutions more prevalently generate trimer-forming peptides useful for the assays and methods of the invention. While one of skill in the art, aware of Bewley's disclosure, might also contemplate development of a HR1/HR2 binding assay such as the one described in Ferrer, such a practitioner would still lack the appropriate

starting materials (the peptides of the present claims with particularly useful substitutions thereto) for the methods claimed herein and would lack the motivation – i.e., any motivation beyond a mere hint that other peptides might be "obvious to try" – to consider use of HR1 peptides other than the narrowly prescribed modified-36-mers of Bewley, without the guidance offered by the present disclosure to promote the undertaking and suggest the reward and expectancy of success for such efforts. As such, Applicants believe that the grounds for this rejection have been overcome, and Applicants ask that the Examiner reconsider and withdraw this present rejection under 35 U.S.C. § 103(a).

3. The Rejection Under 35 U.S.C. 103(a) Based On Bewley et al. (2002) In View Of Ferrer et al. (1999) and Barney et al. (1999) Should Be Withdrawn

The Examiner further rejects claims 2, 3, 5, 6, 18, 19, 21 and 22 under 35 U.S.C. § 103(a) as unpatentable over Bewley in view of Ferrer et al. (as above), further in view of Barney et al. (1999). The Examiner suggests that one of skill in the art at the time of filing, in view of Bewley, Ferrer and Barney, would be motivated to modify (e.g., with carrier groups) synthetic peptides of the HR1 region of HIV gp41 and make "conservative" substitutions in the various portions of heptadic repeats therein.

In response, Applicants respectfully disagree with this interpretation, yet note that the claims have been amended, without prejudice, in such a manner that the synthetic peptide "initial materials" of the present invention are different and longer than the two 36-mer peptides described by Bewley, and feature a special emphasis on useful substitutions in a particular heptad repeat cluster within the HR1 sequence. Even should one of skill in the art at the time of the present filing have considered adding carrier groups (or other modifications) to synthetic peptides, such scientists would not have been motivated, based on Bewley (even in view of Ferrer and Barney), to seek out and reasonably expect distinct and longer sequences, with or without conservative (or other) substitutions thereto, to hold any particular promise as being sequences likely to self-associate as trimers in solution (and complex with HR2 peptides) and thus hold any promise as being of any particular use for the assays/methods of present invention, other than perhaps the mere suggestion that such efforts and manipulations might be "obvious to try." Such limited teachings are insufficient to render the present subject matter unpatentable under 35 U.S.C. § 103, and Applicants respectfully ask that the Examiner reconsider and withdraw the present rejection in view of the claims as presently recited.

4. The Rejection Under 35 U.S.C. 103(a) Based On Chan (1997) In View Of Barney (1999) and Ferrer (1999) Should Be Withdrawn

The Examiner rejects claims 1-8 and 17-24 under 35 U.S.C. § 103(a) as unpatentable over Chan et al. (1997) in view of Barney et al. (1999) and Ferrer et al. (1999). It is believed that one of skill in the art at the time of filing, in view of Chan, Barney and Ferrer, would be motivated to modify (e.g., with carrier groups) synthetic peptides of the HR1 region of HIV gp41 and make "conservative" substitutions in the various portions of heptadic repeats therein.

In response, Applicants respectfully disagree with this interpretation, yet reiterate that the claims have been amended, without prejudice, in such a manner that the synthetic peptide used in the present invention are different and longer than the 36-mer peptide described by Chan, and feature emphasis upon substitutions within a particular amino acid "cluster" of HR1 that are especially useful for generating peptides that self-associate as trimers (which, in turn, form complexes with HR2 peptides) and are of particular use for the assays and methods of the invention. Even should one of skill in the art at the time of filing have considered adding carrier groups (or other modifications) to the synthetic peptide disclosed by Chan, such scientists would not have been motivated based on the art to seek out and reasonably expect the distinct, and longer, sequences of the present invention, either with or without conservative substitutions thereto, to offer any particular promise as being sequences likely to self-associate as trimers in solution and serve as particularly useful tools for the assays of the present invention, other than perhaps a limited suggestion that such efforts and manipulations might be "obvious to try." Again, such limited teachings are insufficient to render the present subject matter unpatentable under 35 U.S.C. § 103, and Applicants respectfully ask that the Examiner reconsider and withdraw the present rejection in view of the claims as presently recited.

5. The Rejection Under 35 U.S.C. §112, First Paragraph ("Enablement"), Should Be Withdrawn

The Examiner has previously rejected claims 1-8 and 17-22 under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter not described in the specification in such fashion to convey to one of skill in the relevant art that the inventors possessed the claimed invention at the time of filing. Applicants' acknowledge and appreciate the Examiner's observation that this rejection has been withdrawn in response to Applicants' statement.

The Examiner currently rejects claims 1-8 and 17-24 under 35 U.S.C. § 112, first paragraph, in that the current specification allegedly fails to reasonably enable a person skill in the art to make or use the invention commensurate in scope with the present claims.

In response, Applicants note that the relevant claims have been amended, in an effort to promote clarity, so as, *inter alia*, to restrict the length and further particularize what modifications (e.g., substitutions) may take place in the claimed sequences and where in the sequences that these modifications may occur. Applicants have further provided numerous examples in the specification of the different modifications that may successfully be employed to promote trimeric self-association of the peptides in solution and thus be of particular use in the methods of the invention. The claims clearly present that the self-association of the peptides as trimers is central to the workings of the claimed methods, and other potential candidate peptides may be readily tested for such properties. While not each and every such possible amino acid substitution or modification is explicitly listed or tested in the claims or in the specification, the present disclosure offers sufficient guidance such that one of skill in the art not only would readily understand and be able to practice the current invention, but would also be enabled to readily select and test avenues of particular promise (particular sequences and modifications thereto) in developing other peptides for the screening assays of the invention. While a comprehensive testing of candidate sequences of interest by other scientists to determine trimer formation thereof might entail time-consuming, careful effort, such testing nonetheless would not require undue experimentation or inventive work upon the part of such scientists, but would rather entail essentially routine laboratory practices. Applicants believe that the present amendments to the claims therefore obviate the present rejection under 35 U.S.C. § 112, first paragraph, and Applicants ask that the Examiner reconsider and withdraw this rejection under 35 U.S.C. § 112, first paragraph. Applicants further respectfully request that the Examiner grant a prompt allowance for the pending claims as currently recited.

CONCLUSION

Applicants respectfully request entry of the amendment and remarks into the file of the application. Should any issue remain, the Examiner is respectfully encouraged to telephone the undersigned to discuss the same. In the event any additional fee is required, beyond that which is included herewith, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

by Greg Gibbs Reg. No. 51,036

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Enclosures